

JUN 3 1999

510(k) Summary
OPERA CUP

K 99 1538

All- polyethylene acetabular flanged component

Submitter's name: Smith & Nephew, Inc., Orthopaedic Division
Submitter's address: 1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number: 901/399-5153
Contact person: Janet Johnson Green
Date summary prepared: April 26, 1999
Trade or proprietary device name: OPERA CUP

Common or usual name: Acetabular component
Classification name: Title 21 CFR 888.3353 Hip Joint metal/ ceramic/
polymer semi-Constrained cemented or non-porous
uncemented Prosthesis.

Device Product Code and Panel Code: 87JDI

Substantially Equivalent, Legally Marketed Predicate Devices:

Spectron All-Polyethylene Acetabular Component
Depuy OGEE® Flanged Acetabular Cup
Depuy All-Polyethylene Cemented Acetabular Cup

Subject device description:

The **Opera Cup** all-polyethylene acetabular component is a hemispherical cup with a non-concentric flange protruding from its rim. The component is made from Ultra-High-Molecular-Weight Polyethylene (ASTM F-648). The outer surface of the hemisphere has concentric grooves around the periphery. A wire marker is located in the one of the grooves for implant location on X-ray. The flange is designed to be trimmed to conform with the anatomy of the individual patient to allow closure at the acetabular rim; thus ensuring good cement containment and pressurization.

Subject device intended use:

The Opera Cup is indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Technological Characteristics:

The Opera Cup is similar to the legally marketed devices listed above in that these devices are indicated for total hip replacement, are manufactured from similar or like materials, and are similar in technological characteristics.



JUN 3 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Janet Johnson Green
Clinical and Regulatory Affairs
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K991538
Trade Name: Opera Cup Flanged Acetabular Components
Regulatory Class: II
Product Codes: JDI and LZO
Dated: April 30, 1999
Received: May 3, 1999

Dear Ms. Green:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

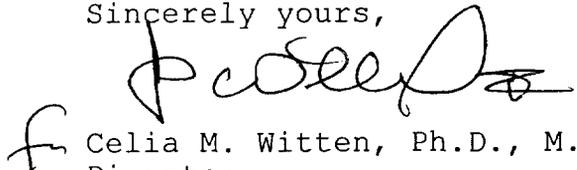
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


f Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991538

Device Name: Opera Cup Flanged Acetabular Components

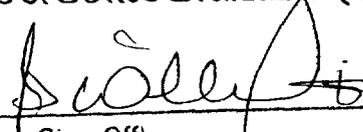
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K9915

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format)